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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,684	09/28/2006	Hiroshi Kase	00005.001304.	2139

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EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
07/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/594,684	KASE ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12, 14, 15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/8/2008 (3 pgs)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

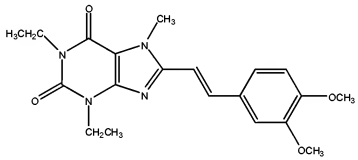
DETAILED ACTION

Election/Restrictions

Applicant's election of Group II, claims 12, 14, and 15, in the reply filed on 5/8/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-11 and 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicants also elect Compound No. 2 from Table 1 on page 41 of the instant specification.



Compound 2.

The restriction requirement is hereby made FINAL.

Claim Objections

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is

required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Specifically, Claim 14 attempts to further limit fibromyalgia syndromes with disorders such as chronic fatigue syndrome and temporomandibular joint disorder, which appear be directed to a broader patient population than the term they are limiting, i.e. including patients who don't have fibromyalgia syndrome but still have the further limited disorder.

Claim Rejections – 35 U.S.C. § 112 - 2nd Paragraph – Antecedent Basis

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "agent as claimed in Claim 11". There is insufficient antecedent basis for this limitation because Claim 11 is currently withdrawn from consideration.

Claim 14 includes subject matter outside the scope of claim 12, from which claim 14 depends. Specifically, conditions such as chronic fatigue syndrome and temporomandibular joint disorder appear to include a broader patient population than the patient population of claim 12, namely those patients having fibromyalgia syndrome.

Claim Rejections - 35 USC § 112 1st Paragraph – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a treatment comprising administering a therapeutic agent, does not reasonably provide enablement for treatment comprising administering a prophylactic agent. Note, while the claim is directed toward a method of treatment, the inclusion of administration of a "prophylactic agent" suggests that treatment includes prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC

1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method of treating fibromyalgia using a specific compound. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites Uceyler (A Systematic Review on the Effectiveness of Treatment With Antidepressants in Fibromyalgia Syndrome, Vol. 59, No. 9, September 15, 2008, pp 1279–1298). Uceyler teaches that patients diagnosed

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

with fibromyalgia incur high direct and indirect costs and that effective treatment options are therefore needed for medical and economic reasons (p.1279, Intro, 1st para). Given the unpredictability of treatment, one would infer the prevention would similarly be unpredictable.

2. The breadth of the claims

Since the instant specification provides no limiting definition of the term "prevention", the term will be interpreted expansively. The term "prevention" may vary widely in meaning, from "preventing" a disease from occurring to "preventing" it from progressing. Nor is the term limited by any time frame. Similarly, the term "prophylactic" is not limited by the specification, and will therefore be interpreted expansively.

The claims are thus very broad insofar as they suggest that one will not experience the disease when taking the claimed agent; that should one get the disease, it will not worsen; or that following its treatment, it will not recur. While such "prevention" or "prophylaxis" might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for practicing the claimed invention in its "full scope". No reasonably specific guidance is provided concerning useful therapeutic protocols for prevention or prophylaxis. The working examples provide data only on treating hyperalgesia, not treatment of fibromyalgia or prevention

of the same (Instant specification pages 42-45).

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, one skilled in the art would not accept the assertion that the instantly claimed agents could be predictably used for the prevention or treatment of fibromyalgia when data shows only that hyperalgesia was treated in healthy rats by administered the drug. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its "full scope" a person of ordinary skill in the art would have to engage in undue experimentation, with no reasonable expectation of success.

Claim Rejections – 35 U.S.C. § 103

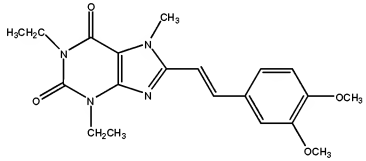
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (U.S. 5,587,378) in view of Ledent (Aggressiveness, hypoalgesia and high blood pressure in mice lacking the adenosine A2a receptor, Nature, Vol. 388, pp 674-678, August 1997 – See IDS dated 1/31/2007).

Suzuki teaches the adenosine A_{2A} receptor antagonist compounds (Col. 1, last para) described in Suzuki include Compound 65 (Col. 21):



Compound 65.

Suzuki does not teach treating fibromyalgia.

Ledent teaches that the A_{2A} receptor agonists are known for treating pain disorders generally, given the difficulty in determining which specific receptor type is treated (p.677, Left Col., Last Para.).[2]

Ledent does not teach the elected compound.

It would have been obvious to one of ordinary skill in the art to administer the adenosine A_{2A} receptor antagonist compounds of Suzuki in order to treat a known pain disorder, such as fibromyalgia, given the antagonistic effect of the A_{2A} receptor is known to reduce pain in patients.

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[2] Stedman's Medical Dictionary 27th Edition defines fibromyalgia as "A syndrome of chronic pain of musculoskeletal origin but uncertain cause".

With regard to claim 14, "generalized fibrositis" is interpreted as being the same as fibromyalgia.[3]

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 14 and 15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,587,378 in view of Ledent (Aggressiveness, hypoalgesia and high blood pressure in mice lacking the adenosine A2a receptor, Nature, Vol. 388, pp 674-678, August 1997 – See IDS dated 1/31/2007).

[3] "fibromyalgia is no longer thought of as an autoimmune disorder, indeed the clinical name associated with the disease was changed from fibrositis to fibromyalgia to specifically remove any connotation of an immune or inflammatory condition". Holman (U.S. 6,277,875) at Column 2, Lines 12-16.

Ledent teaches that the A_{2A} receptor is a drug design target for research dealing with Parkinson's disease and pain disorders (p.677, Left Col., Last Para.).[2]

Ledent does not teach the elected compound.

It would have been obvious to use Compound 65 for treating fibromyalgia because Compound 65 is an A_{2A} antagonist and the A_{2A} receptor has been linked to pain disorders.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. M./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612